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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/743,192 | 12/22/2003 | Peter M. Bonutti | 2500DV2CN2DV3CN7 | 6862 |

7590 03/08/2005

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/743,192 | Applicant(s) BONUTTI, PETER M. | |
| | Examiner Michael Thaler | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/24/04</u> . | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 3731

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This application is described as being a continuation of one of a number of parent applications. There is no basis in the original disclosure of the parent applications for the limitation that the embodiment of the inflatable bladder which has the shape of a wedge when inflated (figures 11 and 11A) as defined in claim 1 also has additional inflatable bladders on the shaft.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 3731

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jakubczak (4,651,717). Jakubczak discloses shaft 214 and inflatable bladder 201 which has the shape of a wedge when inflated. The Jakubczak device is a retractor since it moves tissue. Alternatively, it would have been obvious that the Jakubczak device is a retractor since it moves tissue. As to claim 2, the inflatable bladder 201 in the figure 7 embodiment does not stretch (at least in the lateral direction) since it is located on mesh 700 which apparently does not

Art Unit: 3731

stretch. As to claims 8 and 9, Jakubczak discloses additional inflatable bladders 102 and 206 which are either directly or indirectly on shaft 214.

Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Solano et al. (4,921,478). Solano et al., in figure 5C, disclose shaft 22 and inflatable bladder 16 which has the shape of a wedge when inflated (since it tapers in the distal direction. The Solano et al. device is a retractor since it moves tissue. Alternatively, it would have been obvious that the Solano et al. device is a retractor since it moves tissue. As to claims 5 and 6, shaft 22 is rigid in portion 38 and flexible in portion 36.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solano et al. (4,921,478). Solano et al. fail to disclose a cannula. However, it is old and well known in this art to use a cannula when inserting a catheter in the body in order to obtain the advantage of smoothly and accurately facilitating its insertion. It would have been obvious to use a cannula with the Solano et al. catheter so that it too would have this advantage.

Art Unit: 3731

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haber et al. disclose a rigid shaft.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
2/17/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731